U.S. FOOD & DRUG ADMINISTRATION

Medi-Khan USA Inc.
Attention: Steven Hwang
Medi-Kahn, Inc.
655 North Berry St., Suite A
Brea, CA 92821
Email Address: (b) (6)

February 9, 2023

Re: BK220686 (Formally K083455)
Trade/Device Name: LIPOKIT WITH DISPOSABLE 50CC AFT SYRINGE MODEL ZLK-100
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QKL, QUB

Dear Mr. Hwang:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated May 18, 2009. Specifically, FDA is updating this SE Letter because FDA has assigned your submission a new submission tracking number and created a new product code to better categorize your device technology.

Please update the registration and listing of the device within the FURLS Device Registration and Listing Module according to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053185.htm.

For more information, please refer to the Federal Register Notice *Consolidation of Devices That Process Autologous Human Cells, Tissues, and Cellular and Tissue-Based Products at the Point of Care To Produce a Therapeutic Article* (86 FR 50887, available at https://www.federalregister.gov/documents/2021/09/13/2021-18912/consolidation-of-devices-that-process-autologous-human-cells-tissues-and-cellular-and-tissue-based).

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact the Regulatory Project Manager, Candace Jarvis at (240) 402-8315 or by email at Candace.Jarvis@fda.hhs.gov.

Sincerely,

Wilson W. Bryan, MD
Director
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research

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Medi-Khan(USA) Inc.

Suite # 400, 6033 West Century Boulevard, Los Angeles, CA 90045, USA
Tel. (310) 649-7570 Fax (310) 649-7569

510(k) Summary (21 CFR 807.92(c))

ADMINISTRATIVE INFORMATION

Manufacturer Name: Medi-Khan USA, Inc.
6033 West Century Boulevard
Suite 403
Los Angeles, California 90045

MAY 18 2009

Contact Person: Peter Jung, Vice President & C.O.O.
Tel.: (310) 649-7570
Fax: (310) 649-7569
E-mail: peter2275@gmail.com

Official Correspondent: CALISO Consulting, LLC
Julie Santiago, Sr. Consultant
1516 Oak Street, Suite 312
Alameda, CA 94501
(510) 864-0463

Establishment Registration Number: 3007134825

Date prepared: October 23, 2008

DEVICE CLASSIFICATION AND PRODUCT CODE

As shown in 21 CFR 878.5040 Suction Lipoplasty Systems are defined as devices consisting of collection bottles, cannulas, and connecting tubing for use in aesthetic body contouring procedures. Suction Lipoplasty Systems are classified as Class II. They have been assigned Product Code MUU.

INTENDED USE

The Lipokit is used in the tumescent injection, aspiration, harvesting, filtering and transferring of autologous fat tissue.

The Lipokit is intended for use in the following surgical specialties when the aspiration of soft tissue is desired:

- Plastic and Reconstructive Surgery
- General Surgery
- Dermatological Surgery
- Obstetrician & Gynecological Surgery
- Cosmetic Surgery

The Lipokit is indicated for use when harvesting of highly concentrated pure fatty tissues for aesthetic body and facial contouring is desired.

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DEVICE DESCRIPTION

Design Characteristics

The Lipokit with disposable 50cc AFT Syringe is composed of one centrifuge unit with a motor for suction and positive pressure; a 50cc AFT (autologous fat transfer) syringe with weight-mesh piston, a cannula and other ancillary parts. The vacuum and positive pressures are controlled using a foot pedal control switch.

The Lipokit is a sterile, single-use, manual device consisting of a cannula, and a tissue collection container (the 50cc AFT Syringe) that relies on the centrifuge unit for its energy supply. The cannula is attached directly to the 50cc AFT Syringe which simplifies and reduces the steps needed in the collection, filtering and transfer of the autologous fat. In so doing, the harvested fat is less traumatized and risk of contamination is lowered because the fat never leaves the harvesting syringe until re-injection. The cannula is a hollow tube with an opening near the tip to communicate the centrifuge unit to the tissues and subsequently aspirate, harvest and filter subcutaneous fatty tissues from the patient into the collection container (the 50cc AFT Syringe).

The stainless steel cannula that contacts the patient is provided in various sizes ranging from 2.5 – 4.0 mm in diameter. The tip region of the cannula may have a single or multiple openings that range in size from 170mm to 260mm in length distributed uniformly or randomly throughout the end of the cannula.

The 50cc AFT Syringe is a polymeric 50cc volume luer-lock style, single-use syringe consisting of a polypropylene barrel with printed graduations and a weight-mesh piston composed of polycarbonate.

Material Composition

The components of Lipokit that have direct patient contact are fabricated from surgical stainless steel.

Sterility

The 50cc AFT Syringe is sterilized by ethylene oxide (EtO) gas.

In Vitro Testing

Mechanical testing of Lipokit demonstrates that the device is substantially equivalent to the predicate devices.

EQUIVALENCE TO MARKET PRODUCT

The Lipokit with disposable 50cc AFT Syringe shares indications and design principles with the following predicate devices which have been determined by FDA to be substantially equivalent to premarket devices: Shippert Medical Tissu-Trans (K050797), Cytori AFT System (K072587) and MacroPore Puricel Lipoplasty System (K042261); Class I and Class II Medical Devices that were cleared for Marketing in the United States under K050797, K072587 and K042261 respectively.

Indications for Use

The Lipokit with disposable 50cc AFT Syringe and the predicate devices are substantially equivalent with respect to their indications for use, as they are all indicated for the same surgical procedures of aspirating, harvesting, filtering, and transferring autologous tissues.

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Design and Materials

The design and materials of the Lipokit with disposable 50cc AFT Syringe and the predicate devices {Shippert Medical TissueTrans™ (K050797), Macropore Puricel Lipoplasty System (K042261) and Cytori AFT System (K072587)} are substantially equivalent, as they are all single-use polymer constructed, manually operated systems that utilize manual or external sources of vacuum to withdraw, hold, and/or inject fluids/tissues into the body. The Lipokit with disposable 50cc AFT Syringe is substantially equivalent to the Tissu-Trans™ (K050797) predicate device, as they both use a polypropylene piston syringe to collect the autologous fat as well as re-inject the fat into the patient at desired locations. Lipokit, like Tissu-Trans™ (K050797) decreases the number of steps a physician must take to process the fat for re-injection. The fat remains in a sterile field at all times with Lipokit, thus reducing the risk of infection.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 18 2009

Medi-Khan (USA), Inc.
% CALISO Consulting, LLC
Ms. Julie C. Santiago
1516 Oak Street, Suite 312
Alameda, California 94501

Re: K083455
Trade/Device Name: Lipokit with disposable 50cc AFT Syringe
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: II
Product Code: MUU
Dated: April 22, 2009
Received: April 22, 2009

Dear Ms. Santiago:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at

(240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Tel. (310) 649-7570 Fax (310) 649-7569

Indications for Use

510(k) Number (if known):

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Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krone for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K083455